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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 529,205	08/21 2000	Seishi Kato	GIN-6712CPUS	9088

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[REDACTED] EXAMINER

BUNNER, BRIDGET E

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1647

DATE MAILED: 07/15/2003

[Signature]

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/529,205	KATO ET AL.
	Examiner	Art Unit
	Bridget E. Bunner	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 January 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 7-9, 13-19, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 7-9, 13-19, 21 and 22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3 Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a))

* Translation of the title or abstract of the foreign application is not required.

- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121

Attachment(s)

- Non-USPTO related document(s) _____
 Non-USPTO related document(s) _____
 Information Disclosure Statement(s) (37 CFR 1.14) _____

- Non-USPTO related document(s) _____
 Non-USPTO related document(s) _____
 Information Disclosure Statement(s) (37 CFR 1.14) _____

DETAILED ACTION

Continued Prosecution Application

The Request for Continued Examination (RCE) filed on 09 January 2003 (Paper No. 24) under 37 CFR 1.114 based on parent Application No. 09/529,205 is acceptable and an RCE has been established. An action on the RCE follows.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

It is noted to Applicant that the amendments filed on 16 May 2002 (Paper No. 16) and 08 October 2002 (Paper No. 21) had been previously entered and considered by the Examiner.

Claims 7-9, 13-19, and 21-22 are under consideration in the instant application.

Claim Rejections - 35 USC § 101 and §112, first paragraph

1. Claims 7-9, 13-19, and 21-22 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation.

2. Claims 7-9, 13-19, and 21-22 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth below, one skilled in the art clearly would not know how to use the claimed invention.

the amino acid sequence of SEQ ID NO: 1. The claims recite an isolated nucleic acid

comprising a nucleotide sequence that is at least 95% identical to the nucleotide sequence set forth in SEQ ID NO: 11. The claims also recite an isolated nucleic acid molecule comprising a nucleotide sequence which is complementary to the nucleotide sequence of claims 7, 8, or 9. The claims are directed to an isolated nucleic acid molecule comprising the nucleic acid molecule of claims 7, 8, or 9, and a nucleotide sequence encoding a heterologous polypeptide. The claims are further directed to an expression system comprising the polynucleotide that produces the polypeptide, a recombinant host cell, a process of producing a recombinant host cell and polypeptide, and a method for preventing, treating, or ameliorating a medical condition by administering a composition comprising the polypeptide.

The specification does not teach that the polynucleotide and polypeptide of the instant application have a specific and substantial asserted utility or a well established utility. Since the specification of the instant application does not disclose any methods or working examples that indicate the polynucleotide and polypeptide of the instant application exhibit similar activities of other proteins, particularly Sea-2, the skilled artisan would not be able to categorize the polynucleotide and polypeptide of the instant application. The assertion that the disclosed protein has biological activities similar to Sea-2 is not credible in the absence of supporting evidence, because the relevant literature reports numerous examples of polypeptide families wherein individual members have distinct, and even opposite, biological activities. Additionally, certain positions in the amino acid sequence are critical to the protein's structure/function

can tolerate only relatively conservative substitutions or no substitutions. The specification

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provides little or no guidance beyond the mere presentation of sequence data to enable one or ordinary skill in the art to determine, without undue experimentation, the positions in the protein and DNA which are tolerant to change and the nature and extent of changes that can be made in these positions. Furthermore, although Applicant asserts that the polypeptide of the instant application is isolated from tissues of human stomach cancer, there are no methods or working examples that indicate the polypeptide is overexpressed as compared to normal stomach tissue or that the polypeptide is present in any other tissues.

Applicant has previously asserted (08 October 2002, Paper No. 21) that the USPTO recognizes that homology between known and unknown proteins is sufficient to ascribe the known protein's function to the unknown. Applicant indicates that the instant invention most resembles the fact pattern set forth in Example 10 of the "Revised Interim Utility Guidelines Training Materials". Applicant's arguments have been fully considered but are not found persuasive. The polynucleotide sequence in the example has high homology to DNA ligase encoding nucleic acids. In this example, DNA ligases have a well-established utility in the art based on this class of protein's ability to ligate DNA. However, the polynucleotide and polypeptide of the instant application are not supported by a specific and asserted utility or a well established utility although Applicant asserts that the claimed polypeptide of SEQ ID NO: 1 is homologous to the existing Sea-2 protein. Additionally, there is little doubt that, after complete characterization, this DNA and protein, may be found to have a specific and substantial credible

analogous to that which was addressed in *Bromer v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct. 1966).

in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. Applicant is welcome to submit any evidence in the form of a declaration under 37 C.F.R. 1.132.

Applicant also argues in the Responses of 08 October 2002 and 16 May 2002 (Paper Nos. 18 and 21, respectively) that the isolated nucleic acid molecule of SEQ ID NO: 11 and the polypeptide of SEQ ID NO: 1 could be used as research tools to better characterize prior art compounds. Applicant's assertion that the isolated nucleic acid molecule of SEQ ID NO: 1 could be used as a research tool to better characterize the activities of peptides in the prior art is not credible, specific, or substantial. Such assays can be performed with any polynucleotide or polypeptide. The specification of the instant application discloses nothing specific and substantial about the claimed polynucleotides and proteins encoded by the polynucleotide and significant experimentation would be required of the skilled artisan to determine the activity of the polypeptide encoded by the claimed polynucleotide. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by Au-Young, J. (U.S. Patent 5,856,136).

Au-Young teaches an isolated nucleic acid sequence *comprising* a nucleotide sequence that is at least 95% identical to the nucleotide sequence set forth in SEQ ID NO: 1 of the instant application (See nucleotides 7-375 of SEQ ID NO: 4 of Au-Young; See also sequence alignment attached to this Office Action as Appendix A.)

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

Elizabeth C. Kemmerer

BEB
Art Unit 1647
July 9, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER